HFA-305

Date of Approval: OCT 28 2004

FREEDOM OF INFORMATION SUMMARY

Supplemental NADA 141-213

METACAM

Meloxicam Oral Suspension

METACAM (meloxicam) Oral Suspension is indicated for the control of pain and inflammation associated with osteoarthritis in dogs.

Sponsored by:

Boehringer Ingelheim Vetmedica, Inc.

141-213

FOIS 1

Table of Contents

FREEDOM OF INFORMATION SUMMARY

1. GENERAL INFORMATION:

a.	File Number:	NADA 141-213
b.	Sponsor:	Boehringer Ingelheim Vetmedica, Inc. 2621 North Belt Highway St. Joseph, MO 64506-2002 Drug Labeler Code: 000010
c.	Established Name:	meloxicam
d.	Proprietary Name:	METACAM Oral Suspension
e.	Dosage Form:	Oral Suspension
f.	How Supplied:	0.5 mg/mL: 15 and 30 mL bottles 1.5 mg/mL: 10, 32 and 100 mL botttles
g.	How Dispensed:	Rx
h.	Amount of Active Ingredients:	0.5 mg/mL and 1.5 mg/mL
i.	Route of Administration:	This product is to be administered orally either mixed with food or placed directly in the mouth.
j.	Species/Class:	Dogs
k.	Recommended Dosage:	Always provide client information sheet with prescription. METACAM Oral Suspension should be administered initially at 0.09 mg/lb (0.2 mg/kg) body weight only on the first day of treatment. For all treatments after day 1, METACAM Oral Suspension should be administered once daily at a dose of 0.045 mg/lb (0.1 mg/kg). The syringe is calibrated to deliver the daily maintenance dose in pounds.
l.	Pharmacological Category:	Non steroidal anti-inflammatory (NSAID)

m. Indications:	METACAM Oral Suspension is indicated for the control of pain and inflammation associated with osteoarthritis in dogs.
n. Effect of Supplement:	This supplement to NADA 141-213 provides revisions to 21 CFR 520.1350 (1) *Amount*. To change the format to read "administered initially at 0.09 mg/lb (0.2 mg/kg) body weight only on the first day of treatment. For all treatments after day 1, METACAM Oral Suspension should be administered once daily at a dose of 0.045 mg/lb (0.1 mg/kg)." This supplement also provides for revisions to labeling, including minor changes facilitating use of the drug and the addition of a Post-Approval section.

2. EFFECTIVENESS:

a. Dosage Characterization:

Refer to the original Freedom of Information summary dated April 15, 2003.

b. Substantial Evidence:

Refer to the original Freedom of Information summary dated April 15, 2003.

3. TARGET ANIMAL SAFETY:

Refer to the original Freedom of Information summary dated April 15, 2003.

4. HUMAN SAFETY:

This drug is intended for use in dogs, which are non-food animals. Because this new animal drug is not intended for use in food-producing animals, data on human safety pertaining to drug residues in food were not required for approval of this NADA.

Human Warnings are provided on the product label as follows: Not for use in humans. Keep this and all medications out of reach of children. Consult a physician in case of accidental ingestion by humans.

5. AGENCY CONCLUSIONS:

The data submitted in support of this NADA satisfy the requirements of section 512 of the Federal Food, Drug, and Cosmetic Act and 21 CFR Part 514 of the implementing regulations. The data demonstrate that METACAM Oral

Suspension when used under the labeled conditions of use is safe and effective for the control of pain and inflammation associated with osteoarthritis in dogs.

The drug is restricted to use by or on the order of a licensed veterinarian because professional expertise is needed to diagnose canine osteoarthritis and to monitor response to treatment.

This approval does not qualify for marketing exclusivity under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act.

Meloxicam is under the following U.S. patent number:

U.S. Patent Number	Date of Expiration
6,184,220	February 6, 2021

6. ATTACHMENTS:

Facsimile Labeling is attached as indicated below:

a. Package insert/Client Information Sheet

b. Box

c. Bottle

d. Shipping label

Labeling is included for the 15 mL container of the 0.5 mg/mL concentration
the 30 mL container of the 0.5 mg/mL concentration
the 10 mL container of the 1.5 mg/mL concentration
the 32 mL container of the 1.5 mg/mL concentration
the 100 mL container of the 1.5 mg/mL concentration

Client Information Sheet
For
Metacam® (meloxicam) 0.5 mg/mL Oral Suspension
Non-steroidal anti-inflammatory drug for oral use in dogs only

This summary contains important information about Metacam. You should read this information before you start giving your dog Metacam and review it each time the prescription is refilled. This sheet is provided only as a summary and does not take the place of instructions from your veterinarian. Talk to your veterinarian if you do not understand any of this information or if you want to know more about Metacam.

What Is Metacam?

Metacam is a prescription non-steroidal anti-inflammatory drug (NSAID) that is used to control pain and inflammation (soreness) due to osteoarthritis in dogs. Osteoarthritis (OA) is a painful condition caused by "wear and tear" of cartilage and other parts of the joints that may result in the following changes or signs in your dog: limping or lameness, decreased activity or exercise (reluctance to stand, climb stairs, jump or run, or difficulty in performing these activities) stiffness or decreased movement of joints. Metacam is given to dogs by mouth. Do not use in cats.

What Kind Of Results Can I Expect When My Dog Is On Metacam For OA?

While Metacam is not a cure for osteoarthritis, it can control the pain and inflammation of OA and improve your dog's mobility.
- Response varies from dog to dog but can be quite dramatic.
- In most dogs, improvement can be seen in a matter of days.
- If Metacam is discontinued or not given as directed, your dog's pain and inflammation may come back.

What Dogs Should Not Take Metacam?

Your dog should not be given Metacam if he/she:
- Has had an allergic reaction to meloxicam, the active ingredient of Metacam.
- Has had an allergic reaction (such as hives, facial swelling, or red or itchy skin) to aspirin or other NSAIDs
- Is presently taking aspirin, other NSAIDs, or corticosteroids (unless directed by your veterinarian).

Metacam Should Only Be Given To Dogs

People should not take Metacam. Keep Metacam and all medication out of reach of children. Call your physician immediately if you accidentally take Metacam.

How To Give Metacam To Your Dog.

The actual dose to be given should be prescribed by the veterinarian.

Directions for Administration:

Dogs under 10 pounds (4.5 kg)

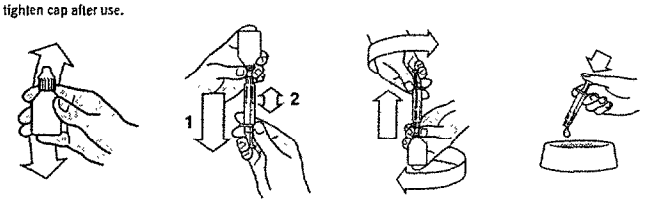
Shake well before use, then remove cap. Particular care should be given with regard to the accuracy of dosing **To prevent accidental overdosing of small dogs, administer drops on food only, never directly into the mouth.** Carefully measure suspension onto food to assure that the correct dose is given before presentation of the food to the dog. The syringe provided with the meloxicam concentration of 0.5 mg/mL cannot be used to measure doses for dogs weighing less than 1 lb (0.45 kg).

For dogs less than 1 lb (0.45 kg), Metacam® Oral Suspension can be given using the dropper bottle: two drops for each pound of body weight for the 0.5 mg/mL concentration (five drops for each kilogram of body weight), dropped directly onto the food.

For dogs between 1-10 pounds, Metacam® Oral Suspension can be given by drops or by using the measuring syringe provided in the package (see dosing procedure below). The syringe fits on to the bottle and has a scale beginning at 1 lb, designed to deliver the daily maintenance dose (0.05 mg/lb or 0.1 mg/kg). When using the syringe, the dog's weight should be rounded down to the nearest 1 pound increment. Replace and tighten cap after use.

Dogs over 10 pounds (4.5 kg)

Shake well before use then remove cap. Metacam® Oral Suspension may be either mixed with food or placed directly into the mouth. Particular care should be given with regard to the accuracy of dosing. Metacam® Oral Suspension can be given using the measuring syringe provided in the package (see dosing procedure below). The syringe fits on to the bottle and has a scale in pounds designed to deliver the daily maintenance dose (0.05 mg/lb or 0.1 mg/kg). When using the syringe, the dog's weight should be rounded down to the nearest 1 lb increment. Alternatively, Metacam® Oral Suspension can be given using the dropper bottle: two drops for each pound body weight for the 0.5 mg/mL concentration (five drops for each kilogram of body weight). Replace and tighten cap after use.



Shake bottle well. Push down and unscrew bottle top. Attach the dosing syringe to the bottle by gently pushing the end onto the top of the bottle.

Turn the bottle/syringe upside down. Pull the plunger out until the black line on the plunger corresponds to the dog's body weight in pounds.

Turn the bottle right way up and with a twisting movement separate the dosing syringe from the bottle

Push the plunger to empty the contents of the syringe

TEAR AT PERFORATION

6014011-00-0410

Client Information Sheet ↑
(Tear at perforation)

Boehringer Ingelheim

Professional Insert ↓

NADA 141-213, Approved by FDA

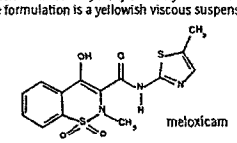
Metacam®

(meloxicam) 0.5 mg/mL Oral Suspension
(equivalent to 0.02 mg per drop)

Non-steroidal anti-inflammatory drug for oral use in dogs only

Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Description: Meloxicam is a Non-Steroidal Anti-Inflammatory (NSAID) drug of the oxicam class. Each milliliter of Metacam® Oral Suspension contains meloxicam equivalent to 0.5 milligrams and sodium benzoate (1.5 milligrams) as a preservative. The chemical name for Meloxicam is 4-Hydroxy-2-methyl-N-(5-methyl-2-thiazolyl)-2H-1,2-benzothiazine-3-carboxamide-1, 1-dioxide. The formulation is a yellowish viscous suspension with the odor of honey.



meloxicam

Clinical Pharmacology: Meloxicam has nearly 100% bioavailability when administered orally with food. The terminal elimination half life after a single dose is estimated to be approximately 24 hrs (+/-30%) regardless of route of administration. There is no evidence of statistically significant gender differences in drug pharmacokinetics. Drug bioavailability, volume of distribution, and total systemic clearance remain constant up to 5 times the recommended dose for use in dogs. However, there is some evidence of enhanced drug accumulation and terminal elimination half-life prolongation when dogs are dosed for 45 days or longer.

Peak drug concentrations can be expected to occur within about 7.5 hrs after oral administration. Corresponding peak concentration is approximately 0.464 mcg/mL following a 0.2 mg/kg oral dose. The drug is 97% bound to canine plasma proteins.

Indications: Metacam® Oral Suspension is indicated for the control of pain and inflammation associated with osteoarthritis in dogs.

Dosage and Administration: Always provide client information sheet with prescription. Metacam® Oral Suspension should be administered initially at 0.09 mg/lb (0.2 mg/kg) body weight only on the first day of treatment. For all treatments after day 1, Metacam® Oral Suspension should be administered once daily at a dose of 0.045 mg/lb (0.1 mg/kg). The syringe is calibrated to deliver the daily maintenance dose in pounds.

Directions for Administration:

Dogs under 10 pounds (4.5 kg)

Shake well before use, then remove cap. Particular care should be given with regard to the accuracy of dosing. To prevent accidental overdosing of small dogs, administer drops on food only, never directly into the mouth. Carefully measure suspension onto food to assure that the correct dose is given before presentation of the food to the dog. The syringe provided with the meloxicam concentration of 0.5 mg/mL cannot be used to measure doses for dogs weighing less than 1 lb (0.45 kg).

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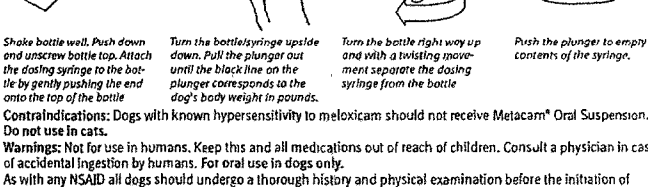
Dogs over 10 pounds (4.5 kg)

Shake well before use then remove cap. Metacam® Oral Suspension may be either mixed with food or placed directly into the mouth. Particular care should be given with regard to the accuracy of dosing. Metacam® Oral Suspension can be given using the measuring syringe provided in the package (see dosing procedure below). The syringe fits on to the bottle and has a scale in pounds designed to deliver the daily maintenance dose (0.05 mg/lb or 0.1 mg/kg). When using the syringe, the dog's weight should be rounded down to the nearest 1 pound increment. Alternatively, Metacam® Oral Suspension can be given using the dropper bottle: two drops for each pound of body weight for the 0.5 mg/mL concentration (five drops for each kilogram of body weight). Replace and tighten cap after use.



Shake bottle well. Push down and unscrew bottle top. Attach the dosing syringe to the bottle by gently pushing the end onto the top of the bottle

Turn the bottle/syringe upside down. Pull the plunger out until the black line on the plunger corresponds to the dog's body weight in pounds.

Turn the bottle right way up and with a twisting movement separate the dosing syringe from the bottle

Push the plunger to empty the contents of the syringe.

Contraindications: Dogs with known hypersensitivity to meloxicam should not receive Metacam® Oral Suspension. **Do not use in cats.**

Warnings: Not for use in humans. Keep this and all medications out of reach of children. Consult a physician in case of accidental ingestion by humans. For oral use in dogs only.

As with any NSAID all dogs should undergo a thorough history and physical examination before the initiation of NSAID therapy. Appropriate laboratory testing to establish hematological and serum biochemical baseline data is recommended prior to and periodically during administration. Owner should be advised to observe their dog for signs of potential drug toxicity and be given a client information sheet about Metacam.

Precautions: The safe use of Metacam® Oral Suspension in dogs younger than 6 months of age, dogs used for breeding, or in pregnant or lactating dogs has not been evaluated. Meloxicam is not recommended for use in dogs with bleeding disorders, as safety has not been established in dogs with these disorders.

As a class, cyclo-oxygenase inhibitory NSAIDs may be associated with gastrointestinal, renal and hepatic toxicity. Sensitivity to drug-associated adverse events varies with the individual patient. Patients at greatest risk for renal toxicity are those that are dehydrated, on concomitant diuretic therapy, or those with existing renal, cardiovascular, and/or hepatic dysfunction. Concurrent administration of potentially nephrotoxic drugs should be carefully approached.

NSAIDs may inhibit the prostaglandins that maintain normal homeostatic function. Such anti-prostaglandin effects may result in clinically significant disease in patients with underlying or pre-existing disease that has not been previously diagnosed. Since many NSAIDs possess the potential to produce gastrointestinal ulceration, concomitant use of Metacam® Oral Suspension with other anti-inflammatory drugs, such as NSAIDs or corticosteroids, should be avoided or closely monitored. Consider appropriate washout times when switching from corticosteroid use or from one NSAID to another in dogs. The use of concomitantly protein-bound drugs with Metacam® Oral Suspension has not been studied in dogs. Commonly used protein-bound drugs include cardiac, anticonvulsant and behavioral medications. The influence of concomitant drugs that may inhibit metabolism of Metacam® Oral Suspension has not been evaluated. Drug compatibility should be monitored in patients requiring adjunctive therapy.

What To Tell/Ask Your Veterinarian Before Giving Metacam

Talk to your veterinarian about:
- The signs of OA you have observed (for example limping, stiffness).
- The importance of weight control and exercise in the management of OA.
- What tests might be done before Metacam is prescribed.
- How often your dog may need to be examined by your veterinarian.
- The risks and benefits of using Metacam.

Tell your veterinarian if your dog has ever had the following medical problems:
- Experienced side effects from Metacam or other NSAIDs, such as aspirin
- Digestive upset (vomiting and/or diarrhea)
- Liver disease
- Kidney disease

Tell your veterinarian about:
- Any other medical problems or allergies that your dog has now or has had.
- All medicines that you are giving your dog or plan to give your dog, including those you can get without a prescription.

Tell your veterinarian if your dog is:
- Pregnant, nursing or if you plan to breed your dog.

What Are The Possible Side Effects That May Occur In My Dog During Metacam Therapy?

Metacam, like other drugs, may cause some side effects. Serious but rare side effects have been reported in dogs taking NSAIDs. Serious side effects can occur with or without warning and in rare situations result in death.

The most common NSAID-related side effects generally involve the stomach and liver or kidney problems. Look for the following side effects that can indicate your dog may be having a problem with Metacam or may have another medical problem:

- Decrease or increase in appetite
- Vomiting
- Change in bowel movement (such as diarrhea, or black, tarry or bloody stools)
- Change in behavior (such as decreased or increased activity level, incoordination, seizure or aggression)
- Yellowing of gums, skin, or whites of the eyes (jaundice)
- Change in drinking habits (frequency, amount consumed)
- Change in urination habits (frequency, color, or smell)
- Change in skin (redness, scabs, or scratching)

It is important to stop therapy and contact your veterinarian immediately if you think your dog has a medical problem or side effect from Metacam therapy. If you have additional questions about possible side effects, talk to your veterinarian.

Can Metacam Be Given With Other Medicines?

Metacam should not be given with other NSAIDs (for example, aspirin, carprofen, etodolac, deracoxib) or steroids (for example, cortisone, prednisone, dexamethasone, triamcinolone).

Tell your veterinarian about all medicines you have given your dog in the past, and any medicines that you are planning to give with Metacam. This should include other medicines that you can get without a prescription. Your veterinarian may want to check that all of your dog's medicines can be given together.

What Can I Do In Case My Dog Eats More Than The Prescribed Amount?

Contact your veterinarian immediately if your dog eats more than the prescribed amount of Metacam.

What Else Should I Know About Metacam?

This sheet provides a summary of information about Metacam. If you have any questions or concerns about Metacam or osteoarthritis pain, talk to your veterinarian.

As with all prescribed medicines, Metacam should only be given to the dog for which it was prescribed. It should be given to your dog only for the condition for which it was prescribed. It is important to periodically discuss your dog's response to Metacam at regular check ups. Your veterinarian will best determine if your dog is responding as expected and if your dog should continue receiving Metacam.

For technical assistance or to report suspected adverse reactions, call 1-866-METACAM (1-866-638-2226).

Manufactured by:
Boehringer Ingelheim Vetmedica, Inc.
St. Joseph, MO 64506 U.S.A.

Distributed by:
Merial Limited
Duluth, GA 30096-4640 U.S.A.

US Patent 6,184,220

601408L-00-0410
Code 601411, 601421
Revised 10/2004

Boehringer Ingelheim

MERIAL

Adverse Reactions: Field safety was evaluated in 306 dogs. Based on the results of two studies, GI abnormalities (vomiting, soft stools, diarrhea, and inappetance) were the most common adverse reactions associated with the administration of meloxicam. The following table lists adverse reactions and the numbers of dogs that experienced them during the studies. Dogs may have experienced more than one episode of the adverse reaction during the study.

Adverse Reactions Observed During Two Field Studies

Clinical Observation	Meloxicam (n=157)	Placebo (n=149)
Vomiting	40	23
Diarrhea/Soft Stool	19	11
Bloody Stool	1	0
Inappetance	5	1
Bleeding gums after dental procedure	1	0
Lethargy/Swollen Carpus	1	0
Epiphora	1	0

In foreign suspected adverse drug reaction (SADR) reporting over a 9 year period, incidences of adverse reactions related to meloxicam administration included: auto-immune hemolytic anemia (1 dog), thrombocytopenia (1 dog), polyarthritis (1 dog), nursing puppy lethargy (1 dog), and pyoderma (1 dog).

Post-Approval Experience: The following adverse reactions are based on voluntary post-approval reporting. The categories are listed in decreasing order of frequency by body system.
Gastrointestinal: vomiting, anorexia, diarrhea, melena, gastrointestinal ulceration
Urinary: azotemia, elevated creatinine, renal failure
Neurological/Behavioral/Special Sense: lethargy, depression
Dermatological/Immunological: pruritus

In rare situations, death has been reported as an outcome of the adverse events listed above. Renal failure has been reported as an outcome of repeated oral dosing of cats.

To report suspected adverse reactions, to obtain a Material Safety Data Sheet, or for technical assistance, call 1-866-METACAM (1-866-638-2226).

Effectiveness: The effectiveness of meloxicam was demonstrated in two field studies involving a total of 277 dogs representing various breeds, between six months and sixteen years of age, all diagnosed with osteoarthritis. Both of the placebo-controlled, masked studies were conducted for 14 days. All dogs received 0.2 mg/kg meloxicam on day 1. All dogs were maintained on 0.1 mg/kg oral meloxicam from days 2 through 14 of both studies. Parameters evaluated by veterinarians included lameness, weight-bearing, pain on palpation, and overall improvement. Parameters assessed by owners included mobility, ability to rise, limping, and overall improvement.
In the first field study (n=109), dogs showed clinical improvement with statistical significance after 14 days of meloxicam treatment for all parameters. In the second field study (n=48), dogs receiving meloxicam showed a clinical improvement after 14 days of therapy for all parameters; however, statistical significance was demonstrated only for the overall investigator evaluation on day 7, and for the owner evaluation on day 14.

Palatability: Metacam® Oral Suspension was accepted by 100% of the dogs when veterinarians administered the initial dose into the mouth. Metacam® Oral Suspension was accepted by 90% of the dogs (123/136) when administered by owners. Problems associated with administration included refusal of food, resistance to swallowing and salivation.

Safety:

Six Week Study
In a six week target animal safety study, meloxicam was administered orally at 1, 3, and 5X the recommended dose with no significant clinical adverse reactions. Animals in all dose groups (control, 1, 3 and 5X the recommended dose) exhibited some gastrointestinal distress (diarrhea and vomiting). No treatment-related changes were observed in hematological, blood chemistry, urinalysis, clotting time, or buccal mucosal bleeding times.

Necropsy results included stomach mucosal petechiae in one control dog, two dogs at the 3X and one dog at the 5X dose. Other macroscopic changes included areas of congestion or depression of the mucosa of the jejunum or ileum in three dogs at the 1X dose and in two dogs at the 5X dose. Similar changes were also seen in two dogs in the control group. There were no macroscopic small intestinal lesions observed in dogs receiving the 3X dose. Renal enlargement was reported during the necropsy of two dogs receiving the 3X dose and two receiving the 5X dose.

Microscopic examination of the kidneys revealed minimal degeneration or slight necrosis at the tip of the papilla in three dogs at the 5X dose. Microscopic examination of the stomach showed inflammatory mucosal lesions, epithelial regenerative hyperplasia or atrophy, and submucosal gland inflammation in two dogs at the recommended dose, three dogs at the 3X and four dogs at the 5X dose. Small intestinal microscopic changes included minimal focal mucosal erosion affecting the villi, and were sometimes associated with mucosal congestion. These lesions were observed in the ileum of one control dog and in the jejunum of one dog at the recommended dose and two dogs at the 5X dose.

Six Month Study
In a six month target animal safety study, meloxicam was administered orally at 1, 3, and 5X the recommended dose with no significant clinical adverse reactions. All animals in all dose groups (controls, 1, 3, and 5X the recommended dose) exhibited some gastrointestinal distress (diarrhea and vomiting). Treatment related changes seen in hematology and chemistry included decreased red blood cell counts in seven of 24 dogs (four 3X and three 5X dogs), decreased hematocrit in 18 of 24 dogs (including three control dogs), dose-related neutrophilia in one 1X, two 3X and three 5X dogs, evidence of regenerative anemia in two 3X and one 5X dog. Also noted were increased BUN in two 5X dogs and decreased albumin in one 5X dog.

Endoscopic changes consisted of reddening of the gastric mucosal surface covering less than 25% of the surface area. This was seen in three dogs at the recommended dose, three dogs at the 3X dose and two dogs at the 5X dose. Two control dogs exhibited reddening in conjunction with ulceration of the mucosa covering less than 25% of the surface area.

Gross gastrointestinal necropsy results observed included mild discoloration of the stomach or duodenum in one dog at the 3X and in one dog at the 5X dose. Multifocal pinpoint red foci were observed in the gastric fundic mucosa in one dog at the recommended dose, and in one dog at the 5X dose.

No macroscopic or microscopic renal changes were observed in any dogs receiving meloxicam in this six month study.

Microscopic gastrointestinal findings were limited to one dog at the recommended dose, and two dogs at the 3X dose. Mild inflammatory mucosal infiltrate was observed in the duodenum of one dog at the recommended dose. Mild congestion of the fundic mucosa and mild myositis of the outer mural musculature of the stomach were observed in two dogs receiving the 3X dose.

How Supplied:
Metacam® Oral Suspension 0.5 mg/mL: 15 and 30 mL dropper bottles with measuring syringe

Storage: Store at controlled room temperature 59-86°F (15 - 30°C)

Manufactured by:
Boehringer Ingelheim Vetmedica, Inc.
St. Joseph, MO 64506 U.S.A.

Distributed by:
Merial Limited
Duluth, GA 30096-4640 U.S.A.

US Patent 6,184,220

601401L-00-0410
Code 601411, 601421
Revised 10/2004

MERIAL

Non-steroidal anti-inflammatory drug for oral use in dogs only

Warnings: Not for use in humans. Keep out of reach of children. Refer to the package insert for complete warnings and precautions.

US Patent 6,184,220

Manufactured by:
Boehringer Ingelheim Vetmedica, Inc.
St. Joseph, MO 64506 U.S.A.

Distributed by:
Merial Limited
Duluth, GA 30096-4640 U.S.A.

MERIAL

601402L-00-0407
Code 601411

Metacam®

(meloxicam)

0.5 mg/mL Oral Suspension

Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Net Contents: 15 mL

Indications: Metacam® Oral Suspension is indicated for the control of pain and inflammation associated with osteoarthritis in dogs.

Dosage and Administration: Refer to the package insert for complete Dosage and Administration information.

Store at controlled room temperature, 59–86°F (15–30°C).

Lot No: Exp. Date:

Boehringer Ingelheim

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Boehringer
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601403D-00-0410

Metacam®
(meloxicam)
15mL
0.5 mg/mL Oral Suspension

2951

Metacam®
(meloxicam)
0.5 mg/mL Oral Suspension
Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.
Non-steroidal anti-inflammatory drug for oral use in dogs only
Net Contents: 15 mL
NADA 141-213, Approved by FDA

Boehringer Ingelheim

Warnings: Not for use in humans. Keep this and all medications out of reach of children. Consult a physician in case of accidental ingestion by humans. For oral use in dogs only. As with any NSAID all dogs should undergo a thorough history and physical examination before the initiation of NSAID therapy. Appropriate laboratory testing to establish hematological and serum biochemical baseline data is recommended prior to and periodically during administration. For technical assistance or to report suspected adverse reactions, call 1-866-METACAM (1-866-638-2226).

US Patent 6,184,220

Metacam® is a registered trademark of Boehringer Ingelheim Vetmedica GmbH, licensed to Boehringer Ingelheim Vetmedica, Inc.

Manufactured by:
Boehringer Ingelheim Vetmedica, Inc.
St. Joseph, MO 64506 U.S.A.

Distributed by:
Merial Limited
Duluth, GA 30096-4640 U.S.A.

MERIAL

1 2 3 4 5 6 7
8 9 10 11 12

Metacam®
(meloxicam)
0.5 mg/mL Oral Suspension
Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.
Non-steroidal anti-inflammatory drug for oral use in dogs only
Net Contents: 15 mL
NADA 141-213, Approved by FDA

Boehringer Ingelheim

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Lot No.: Exp. Date:

601403D-00-0410

Indications: Metacam® Oral Suspension is indicated for the control of pain and inflammation associated with osteoarthritis in dogs.

Dosage and Administration: Always provide client information sheet with prescription. Metacam® Oral Suspension should be administered initially at 0.09 mg/lb (0.2 mg/kg) body weight only on the first day of treatment. For all treatments after day 1, Metacam® Oral Suspension should be administered once daily at a dosage of 0.045 mg/lb (0.1 mg/kg). The syringe is calibrated to deliver the daily maintenance dose in pounds.

Refer to the package insert for complete dosage and administration information.

Store at controlled room temperature, 59-86°F (15-30°C).

601403D-00-0410
Code 601411

Metacam Oral Suspension, 0.5 mg/mL
(meloxicam)
For Use in Dogs

QUANTITY LOT NO. EXP. DATE

84x15mL

ITEM NUMBER

601411000

10012313601413

Store at controlled room temperature, 59-86°F (15-30°C).

Boehringer Ingelheim Vetmedica, Inc.
St. Joseph, MO 64506 U.S.A

601404C-00-0211

000027

Non-steroidal anti-inflammatory drug for oral use in dogs only

Warnings: Not for use in humans. Keep out of reach of children. Refer to the package insert for complete warnings and precautions.

US Patent 6,184,220

Manufactured by:
Boehringer Ingelheim Vetmedica, Inc.
St. Joseph, MO 64506 U.S.A.

Distributed by:
Merial Limited
Duluth, GA 30096-4640 U.S.A.

MERIAL

601405L-00-0407
Code 601421

Metacam®

(meloxicam)

0.5 mg/mL Oral Suspension

Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Net Contents: 30 mL

Indications: Metacam® Oral Suspension is indicated for the control of pain and inflammation associated with osteoarthritis in dogs.

Dosage and Administration: Refer to the package insert for complete Dosage and Administration information.

Store at controlled room temperature, 59–86°F (15–30°C).

Take Time Observe Label Directions

Lot No: Exp. Date:

Boehringer Ingelheim

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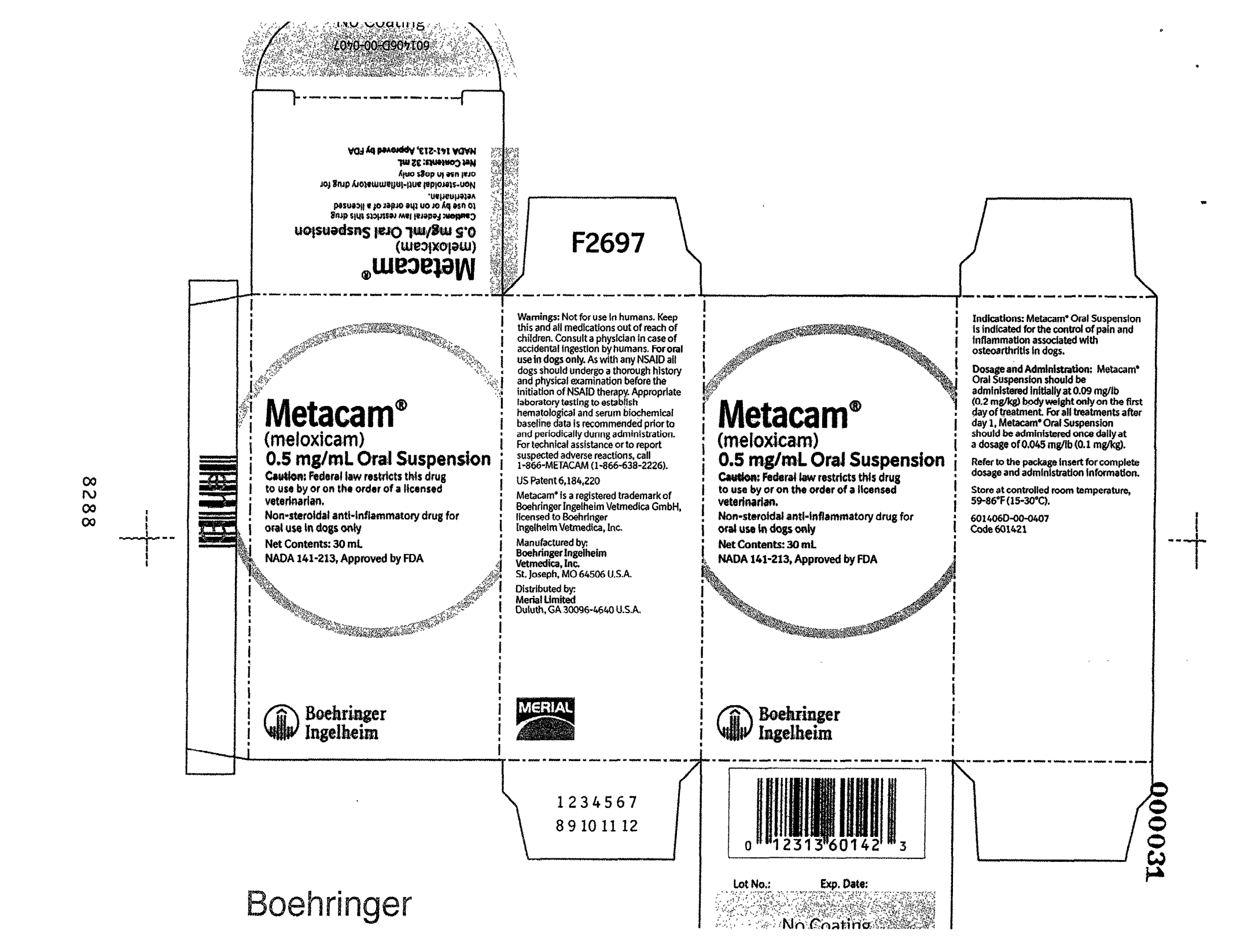
No Coating
601406D-00-0407
Metacam®
(meloxicam)
0.5 mg/mL Oral Suspension
Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.
Non-steroidal anti-inflammatory drug for oral use in dogs only
Net Contents: 32 mL
NADA 141-213, Approved by FDA
F2697
Metacam®
(meloxicam)
0.5 mg/mL Oral Suspension
Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.
Non-steroidal anti-inflammatory drug for oral use in dogs only
Net Contents: 30 mL
NADA 141-213, Approved by FDA
Boehringer Ingelheim
Warnings: Not for use in humans. Keep this and all medications out of reach of children. Consult a physician in case of accidental ingestion by humans. For oral use in dogs only. As with any NSAID all dogs should undergo a thorough history and physical examination before the initiation of NSAID therapy. Appropriate laboratory testing to establish hematological and serum biochemical baseline data is recommended prior to and periodically during administration. For technical assistance or to report suspected adverse reactions, call 1-866-METACAM (1-866-638-2226).
US Patent 6,184,220
Metacam® is a registered trademark of Boehringer Ingelheim Vetmedica GmbH, licensed to Boehringer Ingelheim Vetmedica, Inc.
Manufactured by:
Boehringer Ingelheim Vetmedica, Inc.
St. Joseph, MO 64506 U.S.A.
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MERIAL
1 2 3 4 5 6 7
8 9 10 11 12
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(meloxicam)
0.5 mg/mL Oral Suspension
Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.
Non-steroidal anti-inflammatory drug for oral use in dogs only
Net Contents: 30 mL
NADA 141-213, Approved by FDA
Boehringer Ingelheim
Indications: Metacam® Oral Suspension is indicated for the control of pain and inflammation associated with osteoarthritis in dogs.
Dosage and Administration: Metacam® Oral Suspension should be administered initially at 0.09 mg/lb (0.2 mg/kg) body weight only on the first day of treatment. For all treatments after day 1, Metacam® Oral Suspension should be administered once daily at a dosage of 0.045 mg/lb (0.1 mg/kg).
Refer to the package insert for complete dosage and administration information.
Store at controlled room temperature, 59-86°F (15-30°C).
601406D-00-0407
Code 601421
0 12313 60142 3
Lot No.:
Exp. Date:
No Coating
Boehringer
8288
000031

Client Information Sheet
For
Metacam® (meloxicam) 1.5 mg/mL Oral Suspension
Non-steroidal anti-inflammatory drug for oral use in dogs only

This summary contains important information about Metacam. You should read this information before you start giving your dog Metacam and review it each time the prescription is refilled. This sheet is provided only as a summary and does not take the place of instructions from your veterinarian. Talk to your veterinarian if you do not understand any of this information or if you want to know more about Metacam.

What Is Metacam?

Metacam is a prescription non-steroidal anti-inflammatory drug (NSAID) that is used to control pain and inflammation (soreness) due to osteoarthritis in dogs. Osteoarthritis (OA) is a painful condition caused by "wear and tear" of cartilage and other parts of the joints that may result in the following changes or signs in your dog: limping or lameness, decreased activity or exercise (reluctance to stand, climb stairs, jump or run, or difficulty in performing these activities) stiffness or decreased movement of joints. Metacam is given to dogs by mouth. **Do not use in cats.**

What Kind Of Results Can I Expect When My Dog Is On Metacam For OA?

While Metacam is not a cure for osteoarthritis, it can control the pain and inflammation of OA and improve your dog's mobility.
- Response varies from dog to dog but can be quite dramatic.
- In most dogs, improvement can be seen in a matter of days.
- If Metacam is discontinued or not given as directed, your dog's pain and inflammation may come back.

What Dogs Should Not Take Metacam?

Your dog should not be given Metacam if he/she:
- Has had an allergic reaction to meloxicam, the active ingredient of Metacam.
- Has had an allergic reaction (such as hives, facial swelling, or red or itchy skin) to aspirin or other NSAIDs.
- Is presently taking aspirin, other NSAIDs, or corticosteroids (unless directed by your veterinarian).

Metacam Should Only Be Given To Dogs

People should not take Metacam. Keep Metacam and all medication out of reach of children. Call your physician immediately if you accidentally take Metacam.

How To Give Metacam To Your Dog.

The actual dose to be given should be prescribed by the veterinarian.

Directions for Administration:

Dogs under 10 pounds (4.5 kg)

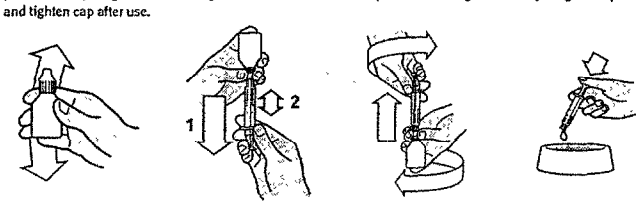
Shake well before use, then remove cap. Particular care should be given with regard to the accuracy of dosing. **To prevent accidental overdosing of small dogs, administer drops on food only, never directly into the mouth.** Carefully measure suspension onto food to assure that the correct dose is given before presentation of the food to the dog. The syringe provided with the meloxicam concentration of 1.5 mg/mL cannot be used to measure doses for dogs weighing less than 5 lbs (2.3 kg).

For dogs less than 5 lbs (2.3 kg), Metacam® Oral Suspension can be given using the dropper bottle: one drop for each pound of body weight for the 1.5 mg/mL concentration (two drops for each kilogram of body weight), dropped directly onto the food.

For dogs between 5 - 10 pounds, Metacam® Oral Suspension can be given by drops or by using the measuring syringe provided in the package (see dosing procedure below). The syringe fits on to the bottle and has a scale beginning at 5 lbs, designed to deliver the daily maintenance dose (0.05 mg/lb or 0.1 mg/kg). When using the syringe, the dog's weight should be rounded down to the nearest 5 pound increment. Replace and tighten cap after use.

Dogs over 10 pounds (4.5 kg)

Shake well before use then remove cap. Metacam® Oral Suspension may be either mixed with food or placed directly into the mouth. Particular care should be given with regard to the accuracy of dosing. Metacam® Oral Suspension can be given using the measuring syringe provided in the package (see dosing procedure below). The syringe fits on to the bottle and has a scale in pounds designed to deliver the daily maintenance dose (0.05 mg/lb or 0.1 mg/kg). When using the syringe, the dog's weight should be rounded down to the nearest 5 pound increment. Alternatively, Metacam® Oral Suspension can be given using the dropper bottle: one drop for each pound of body weight for the 1.5 mg/mL concentration (two drops for each kilogram of body weight). Replace and tighten cap after use.



Shake bottle well. Push down and unscrew bottle top. Attach the dosing syringe to the bottle by gently pushing the end onto the top of the bottle.

Turn the bottle/syringe upside down. Pull the plunger out until the black line on the plunger corresponds to the dog's body weight in pounds.

Turn the bottle right way up and with a twisting movement separate the dosing syringe from the bottle

Push the plunger to empty the contents of the syringe

TEAR AT PERFORATION

6015161L-01-0410

Client Information Sheet ↑
(Tear at perforation)

Boehringer Ingelheim

Professional Insert ↓

NADA 141-213, Approved by FDA

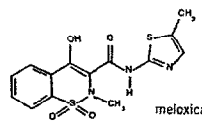
Metacam®

(meloxicam) 1.5 mg/mL Oral Suspension
(equivalent to 0.05 mg per drop)

Non-steroidal anti-inflammatory drug for oral use in dogs only

Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Description: Meloxicam is a Non-Steroidal Anti-Inflammatory (NSAID) drug of the oxicam class. Each milliliter of Metacam® Oral Suspension contains meloxicam equivalent to 1.5 milligrams and sodium benzoate (1.5 milligrams) as a preservative. The chemical name for Meloxicam is 4-Hydroxy-2-methyl-N-(5-methyl-2-thiazolyl)-2H-1,2-benzothiazine-3-carboxamide-1, 1-dioxide. The formulation is a yellowish viscous suspension with the odor of honey.



meloxicam

Clinical Pharmacology: Meloxicam has nearly 100% bioavailability when administered orally with food. The terminal elimination half life after a single dose is estimated to be approximately 24 hrs (+/-30%) regardless of route of administration. There is no evidence of statistically significant gender differences in drug pharmacokinetics. Drug bioavailability, volume of distribution, and total systemic clearance remain constant up to 5 times the recommended dose for use in dogs. However, there is some evidence of enhanced drug accumulation and terminal elimination half-life prolongation when dogs are dosed for 45 days or longer.

Peak drug concentrations can be expected to occur within about 7.5 hrs after oral administration. Corresponding peak concentration is approximately 0.464 mcg/mL following a 0.2 mg/kg oral dose. The drug is 97% bound to canine plasma proteins.

Indications: Metacam® Oral Suspension is indicated for the control of pain and inflammation associated with osteoarthritis in dogs.

Dosage and Administration: Always provide client information sheet with prescription. Metacam® Oral Suspension should be administered initially at 0.09 mg/lb (0.2 mg/kg) body weight only on the first day of treatment. For all treatments after day 1, Metacam® Oral Suspension should be administered once daily at a dose of 0.045 mg/lb (0.1 mg/kg). The syringe is calibrated to deliver the daily maintenance dose in pounds.

Directions for Administration:

Dogs under 10 pounds (4.5 kg)

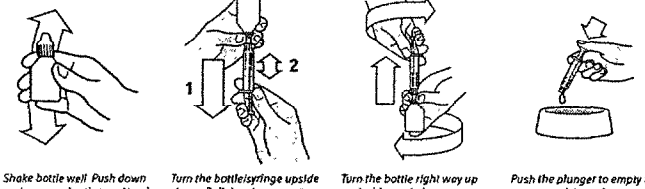
Shake well before use, then remove cap. Particular care should be given with regard to the accuracy of dosing. **To prevent accidental overdosing of small dogs, administer drops on food only, never directly into the mouth.** Carefully measure suspension onto food to assure that the correct dose is given before presentation of the food to the dog. The syringe provided with the meloxicam concentration of 1.5 mg/mL cannot be used to measure doses for dogs weighing less than 5 lbs (2.3 kg).

For dogs less than 5 lbs (2.3 kg), Metacam® Oral Suspension can be given using the dropper bottle: one drop for each pound of body weight for the 1.5 mg/mL concentration (two drops for each kilogram of body weight), dropped directly onto the food.

For dogs between 5 - 10 pounds, Metacam® Oral Suspension can be given by drops or by using the measuring syringe provided in the package (see dosing procedure below). The syringe fits on to the bottle and has a scale beginning at 5 lbs, designed to deliver the daily maintenance dose (0.05 mg/lb or 0.1 mg/kg). When using the syringe, the dog's weight should be rounded down to the nearest 5 pound increment. Replace and tighten cap after use.

Dogs over 10 pounds (4.5 kg)

Shake well before use then remove cap. Metacam® Oral Suspension may be either mixed with food or placed directly into the mouth. Particular care should be given with regard to the accuracy of dosing. Metacam® Oral Suspension can be given using the measuring syringe provided in the package (see dosing procedure below). The syringe fits on to the bottle and has a scale in pounds designed to deliver the daily maintenance dose (0.05 mg/lb or 0.1 mg/kg) When using the syringe, the dog's weight should be rounded down to the nearest 5 pound increment. Alternatively, Metacam® Oral Suspension can be given using the dropper bottle: one drop for each pound of body weight for the 1.5 mg/mL concentration (two drops for each kilogram of body weight). Replace and tighten cap after use.



Shake bottle well. Push down and unscrew bottle top. Attach the dosing syringe to the bottle by gently pushing the end onto the top of the bottle.

Turn the bottle/syringe upside down. Pull the plunger out until the black line on the plunger corresponds to the dog's body weight in pounds.

Turn the bottle right way up and with a twisting movement separate the dosing syringe from the bottle.

Push the plunger to empty the contents of the syringe.

Contraindications: Dogs with known hypersensitivity to meloxicam should not receive Metacam® Oral Suspension. **Do not use in cats.**

Warnings: Not for use in humans. Keep this and all medications out of reach of children. Consult a physician in case of accidental ingestion by humans. **For oral use in dogs only.**

As with any NSAID all dogs should undergo a thorough history and physical examination before the initiation of NSAID therapy. Appropriate laboratory testing to establish hematological and serum biochemical baseline data is recommended prior to and periodically during administration. Owner should be advised to observe their dog for signs of potential drug toxicity and be given a client information sheet about Metacam.

Precautions: The safe use of Metacam® Oral Suspension in dogs younger than 6 months of age, dogs used for breeding, or in pregnant or lactating dogs has not been evaluated. Meloxicam is not recommended for use in dogs with bleeding disorders, as safety has not been established in dogs with these disorders.

As a class, cyclo-oxygenase inhibitory NSAIDs may be associated with gastrointestinal, renal and hepatic toxicity. Sensitivity to drug-associated adverse events varies with the individual patient. Patients at greatest risk for renal toxicity are those that are dehydrated, on concomitant diuretic therapy, or those with existing renal, cardiovascular, and/or hepatic dysfunction. Concurrent administration of potentially nephrotoxic drugs should be carefully approached. NSAIDs may inhibit the prostaglandins that maintain normal homeostatic function. Such anti-prostaglandin effects may result in clinically significant disease in patients with underlying or pre-existing disease that has not been previously diagnosed. Since many NSAIDs possess the potential to produce gastrointestinal ulceration, concomitant use of Metacam® Oral Suspension with other anti-inflammatory drugs, such as NSAIDs or corticosteroids, should be avoided or closely monitored. Consider appropriate washout times when switching from corticosteroid use or from one NSAID to another in dogs. The use of concomitantly protein-bound drugs with Metacam® Oral Suspension has not been studied in dogs. Commonly used protein-bound drugs include cardiac, anticonvulsant and behavioral medications. The influence of

What To Tell/Ask Your Veterinarian Before Giving Metacam

Talk to your veterinarian about:
- The signs of OA you have observed (for example limping, stiffness).
- The importance of weight control and exercise in the management of OA.
- What tests might be done before Metacam is prescribed.
- How often your dog may need to be examined by your veterinarian.
- The risks and benefits of using Metacam.

Tell your veterinarian if your dog has ever had the following medical problems:
- Experienced side effects from Metacam or other NSAIDs, such as aspirin
- Digestive upset (vomiting and/or diarrhea)
- Liver disease
- Kidney disease

Tell your veterinarian about:
- Any other medical problems or allergies that your dog has now or has had.
- All medicines that you are giving your dog or plan to give your dog, including those you can get without a prescription.

Tell your veterinarian if your dog is:
- Pregnant, nursing or if you plan to breed your dog.

What Are The Possible Side Effects That May Occur In My Dog During Metacam Therapy?

Metacam, like other drugs, may cause some side effects. Serious but rare side effects have been reported in dogs taking NSAIDs. Serious side effects can occur with or without warning and in rare situations result in death.

The most common NSAID-related side effects generally involve the stomach and liver or kidney problems. Look for the following side effects that can indicate your dog may be having a problem with Metacam or may have another medical problem:

- Decrease or increase in appetite
- Vomiting
- Change in bowel movement (such as diarrhea, or black, tarry or bloody stools)
- Change in behavior (such as decreased or increased activity level, incoordination, seizure or aggression)
- Yellowing of gums, skin, or whites of the eyes (jaundice)
- Change in drinking habits (frequency, amount consumed)
- Change in urination habits (frequency, color, or smell)
- Change in skin (redness, scabs, or scratching)

It is important to stop therapy and contact your veterinarian immediately if you think your dog has a medical problem or side effect from Metacam therapy. If you have additional questions about possible side effects, talk to your veterinarian.

Can Metacam Be Given With Other Medicines?

Metacam should not be given with other NSAIDs (for example, aspirin, carprofen, etodolac, deracoxib) or steroids (for example, cortisone, prednisone, dexamethasone, triamcinolone).

Tell your veterinarian about all medicines you have given your dog in the past, and any medicines that you are planning to give with Metacam. This should include other medicines that you can get without a prescription. Your veterinarian may want to check that all of your dog's medicines can be given together.

What Can I Do In Case My Dog Eats More Than The Prescribed Amount?

Contact your veterinarian immediately if your dog eats more than the prescribed amount of Metacam.

What Else Should I Know About Metacam?

This sheet provides a summary of information about Metacam. If you have any questions or concerns about Metacam or osteoarthritis pain, talk to your veterinarian.

As with all prescribed medicines, Metacam should only be given to the dog for which it was prescribed. It should be given to your dog only for the condition for which it was prescribed. It is important to periodically discuss your dog's response to Metacam at regular check ups. Your veterinarian will best determine if your dog is responding as expected and if your dog should continue receiving Metacam.

For technical assistance or to report suspected adverse reactions, call 1-866-METACAM (1-866-638-2226).

Manufactured by:
Boehringer Ingelheim Vetmedica, Inc.
St. Joseph, MO 64506 U.S.A.

Distributed by:
Merial Limited
Duluth, GA 30096-4640 U S.A.

US Patent 6,184,220

Metacam® is a registered trademark of Boehringer Ingelheim Vetmedica GmbH, licensed to Boehringer Ingelheim Vetmedica, Inc.

6015171L-01-0410
Code 601511, 601521, 601531
Revised 10/2004

Boehringer Ingelheim

MERIAL

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concomitant drugs that may inhibit metabolism of Metacam® Oral Suspension has not been evaluated. Drug compatibility should be monitored in patients requiring adjunctive therapy.

Adverse Reactions: Field safety was evaluated in 306 dogs. Based on the results of two studies, GI abnormalities (vomiting, soft stools, diarrhea, and inappetance) were the most common adverse reactions associated with the administration of meloxicam. The following table lists adverse reactions and the numbers of dogs that experienced them during the studies. Dogs may have experienced more than one episode of the adverse reaction during the study.

Adverse Reactions Observed During Two Field Studies

Clinical Observation	Meloxicam (n=157)	Placebo (n=149)
Vomiting	40	23
Diarrhea/Soft Stool	19	11
Bloody Stool	1	0
Inappetance	5	1
Bleeding gums after dental procedure	1	0
Lethargy/Swollen Carpus	1	0
Epiphora	1	0

In foreign suspected adverse drug reaction (SADR) reporting over a 9 year period, incidences of adverse reactions related to meloxicam administration included: auto-immune hemolytic anemia (1 dog), thrombocytopenia (1 dog), polyarthritis (1 dog), nursing puppy lethargy (1 dog), and pyoderma (1 dog).

Post-Approval Experience: The following adverse reactions are based on voluntary post-approval reporting. The categories are listed in decreasing order of frequency by body system.
Gastrointestinal: vomiting, anorexia, diarrhea, melena, gastrointestinal ulceration
Urinary: azotemia, elevated creatinine, renal failure
Neurological/Behavioral/Special Sense: lethargy, depression
Dermatological/Immunological: pruritus

In rare situations, death has been reported as an outcome of the adverse events listed above. Renal failure has been reported as an outcome of repeated oral dosing of cats.

To report suspected adverse reactions, to obtain a Material Safety Data Sheet, or for technical assistance, call 1-866-METACAM (1-866-638-2226).

Effectiveness: The effectiveness of meloxicam was demonstrated in two field studies involving a total of 277 dogs representing various breeds, between six months and sixteen years of age, all diagnosed with osteoarthritis. Both of the placebo-controlled, masked studies were conducted for 14 days. All dogs received 0.2 mg/kg on day 1. All dogs were maintained on 0.1 mg/kg oral meloxicam from days 2 through 14 of both studies. Parameters evaluated by veterinarians included lameness, weight-bearing, pain on palpation, and overall improvement. Parameters assessed by owners included mobility, ability to rise, limping, and overall improvement.
In the first field study (n=109), dogs showed clinical improvement with statistical significance after 14 days of meloxicam treatment for all parameters. In the second field study (n=48), dogs receiving meloxicam showed a clinical improvement after 14 days of therapy for all parameters; however, statistical significance was demonstrated only for the overall investigator evaluation on day 7, and for the owner evaluation on day 14.

Palatability: Metacam® Oral Suspension was accepted by 100% of the dogs when veterinarians administered the initial dose into the mouth. Metacam® Oral Suspension was accepted by 90% of the dogs (123/136) when administered by owners. Problems associated with administration included refusal of food, resistance to swallowing and salivation.

Safety:
Six Week Study
In a six week target animal safety study, meloxicam was administered orally at 1, 3, and 5X the recommended dose with no significant clinical adverse reactions. Animals in all dose groups (control, 1, 3 and 5X the recommended dose) exhibited some gastrointestinal distress (diarrhea and vomiting). No treatment-related changes were observed in hematological, blood chemistry, urinalysis, clotting time, or buccal mucosal bleeding times.

Necropsy results included stomach mucosal petechiae in one control dog, two dogs at the 3X and one dog at the 5X dose. Other macroscopic changes included areas of congestion or depression of the mucosa of the jejunum or ileum in three dogs at the 1X dose and in two dogs at the 5X dose. Similar changes were also seen in two dogs in the control group. There were no macroscopic small intestinal lesions observed in dogs receiving the 3X dose. Renal enlargement was reported during the necropsy of two dogs receiving the 3X and two receiving the 5X dose.

Microscopic examination of the kidneys revealed minimal degeneration or slight necrosis at the tip of the papilla in three dogs at the 5X dose. Microscopic examination of the stomach showed inflammatory mucosal lesions, epithelial regenerative hyperplasia or atrophy, and submucosal gland inflammation in two dogs at the recommended dose, three dogs at the 3X and four dogs at the 5X dose. Small intestinal microscopic changes included minimal focal mucosal erosion affecting the villi, and were sometimes associated with mucosal congestion. These lesions were observed in the ileum of one control dog and in the jejunum of one dog at the recommended dose and two dogs at the 5X dose.

Six Month Study
In a six month target animal safety study, meloxicam was administered orally at 1, 3, and 5X the recommended dose with no significant clinical adverse reactions. All animals in all dose groups (controls, 1, 3, and 5X the recommended dose) exhibited some gastrointestinal distress (diarrhea and vomiting). Treatment related changes seen in hematology and chemistry included decreased red blood cell counts in seven of 24 dogs (four 3X and three 5X dogs), decreased hematocrit in 18 of 24 dogs (including three control dogs), dose-related neutrophilia in one 1X, two 3X and three 5X dogs, evidence of regenerative anemia in two 3X and one 5X dog. Also noted were increased BUN in two 5X dogs and decreased albumin in one 5X dog.

Endoscopic changes consisted of reddening of the gastric mucosal surface covering less than 25% of the surface area. This was seen in three dogs at the recommended dose, three dogs at the 3X dose and two dogs at the 5X dose. Two control dogs exhibited reddening in conjunction with ulceration of the mucosa covering less than 25% of the surface area.

Gross gastrointestinal necropsy results observed included mild discoloration of the stomach or duodenum in one dog at the 3X and in one dog at the 5X dose. Multifocal pinpoint red foci were observed in the gastric fundic mucosa in one dog at the recommended dose, and in one dog at the 5X dose.

No macroscopic or microscopic renal changes were observed in any dogs receiving meloxicam in this six month study.

Microscopic gastrointestinal findings were limited to one dog at the recommended dose, and two dogs at the 3X dose. Mild inflammatory mucosal infiltrate was observed in the duodenum of one dog at the recommended dose. Mild congestion of the fundic mucosa and mild myositis of the outer mural musculature of the stomach were observed in two dogs receiving the 3X dose.

How Supplied:
Metacam® Oral Suspension 1.5 mg/mL: 10, 32 and 100 mL dropper bottles with measuring syringe

Storage: Store at controlled room temperature 59-86°F (15 - 30°C).

Manufactured by
Boehringer Ingelheim Vetmedica, Inc.
St. Joseph, MO 64506 U.S.A.

Distributed by
Merial Limited
Duluth, GA 30096-4640 U.S.A.

US Patent 6,184,220

Metacam® is a registered trademark of Boehringer Ingelheim Vetmedica GmbH, licensed to Boehringer Ingelheim Vetmedica, Inc.

6015161L-01-0410
Code 601511, 601521, 601531
Revised 10/2004

MERIAL

Non-steroidal anti-inflammatory drug for oral use in dogs only

Warnings: Not for use in humans. Keep out of reach of children. Refer to the package insert for complete warnings and precautions.

US Patent 6,184,220

Manufactured by:
Boehringer Ingelheim Vetmedica, Inc.
St. Joseph, MO 64506 U.S.A.

Distributed by:
Merial Limited
Duluth, GA 30096-4640 U.S.A.

MERIAL

6015162L-01-0407
Code 601511

Metacam®

(meloxicam)

1.5 mg/mL Oral Suspension

Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Net Contents: 10 mL

Indications: Metacam® Oral Suspension is indicated for the control of pain and inflammation associated with osteoarthritis in dogs.

Dosage and Administration: Refer to the package insert for complete Dosage and Administration information.

Store at controlled room temperature, 59–86°F (15–30°C).

Lot No: Exp. Date:

Boehringer Ingelheim

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Boehringer
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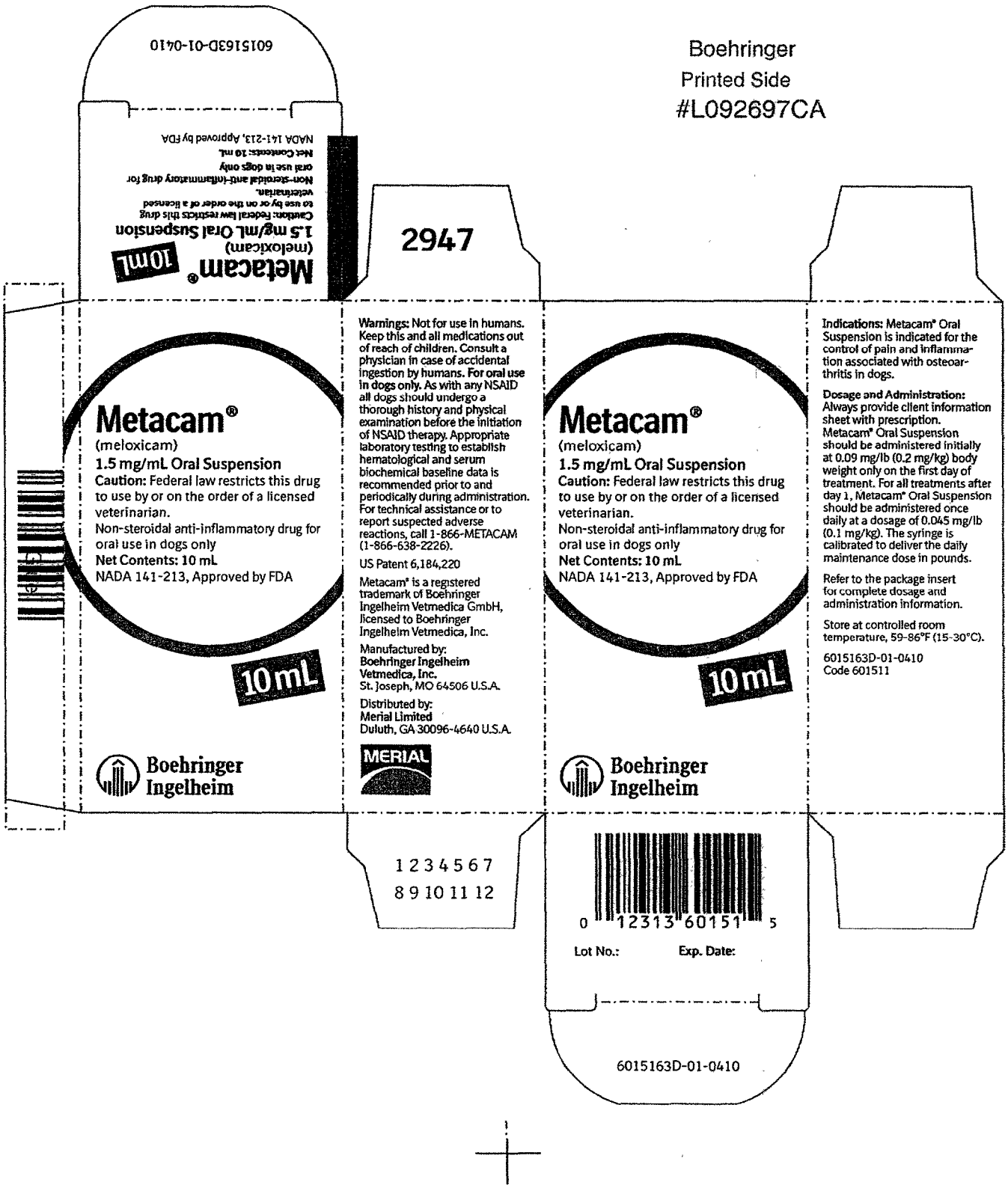

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Metacam Oral Suspension, 1.5 mg/mL
(meloxicam)
For Use in Dogs

QUANTITY LOT NO. EXP. DATE

84x10mL

ITEM NUMBER

601511000

10012313601512

Store at controlled room temperature, 59-86°F (15-30°C).
Manufactured by:
Boehringer Ingelheim Vetmedica, Inc.
St. Joseph, MO 64506 U.S.A.
Distributed by:
Merial Limited
Duluth, GA 30096-4640

6015164C-00-0304

Non-steroidal anti-inflammatory drug for oral use in dogs only

Warnings: Not for use in humans. Keep out of reach of children. Refer to the package insert for complete warnings and precautions.

US Patent 6,184,220

Manufactured by:
Boehringer Ingelheim Vetmedica, Inc.
St. Joseph, MO 64506 U.S.A.

Distributed by:
Merial Limited
Duluth, GA 30096-4640 U.S.A.

MERIAL

6015165L-01-0407
Code 601521

Metacam®

(meloxicam)

1.5 mg/mL Oral Suspension

Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Net Contents: 32 mL

Indications: Metacam® Oral Suspension is indicated for the control of pain and inflammation associated with osteoarthritis in dogs.

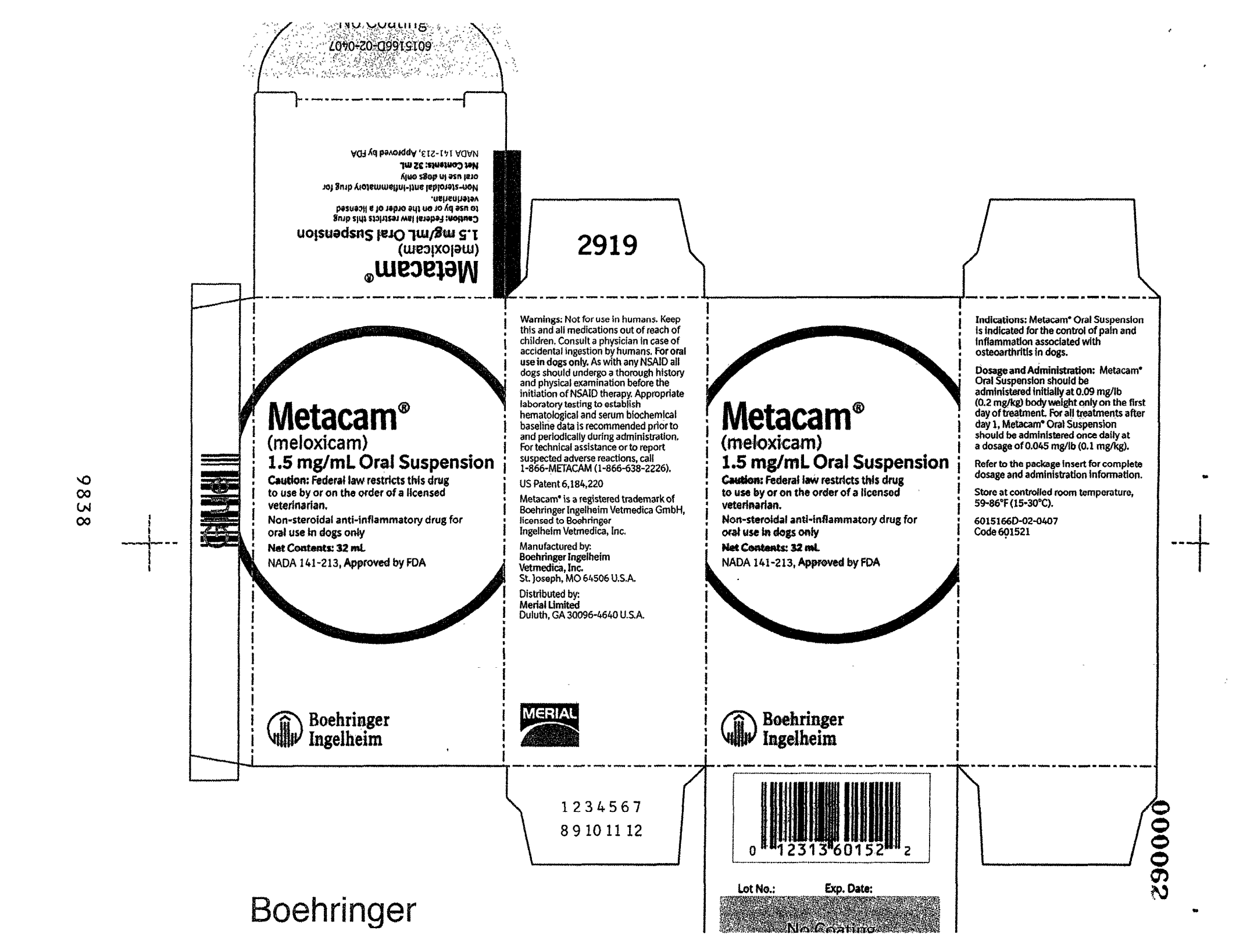
Dosage and Administration: Refer to the package insert for complete Dosage and Administration information.

Store at controlled room temperature, 59–86°F (15–30°C).

Take Time Observe Label Directions

Lot No: Exp. Date:

Boehringer Ingelheim


No Coating
6015166D-02-0407
Metacam®
(meloxicam)
1.5 mg/mL Oral Suspension
Caution: Federal law restricts this drug
to use by or on the order of a licensed
veterinarian.
Non-steroidal anti-inflammatory drug for
oral use in dogs only
Net Contents: 32 mL
NADA 141-213, Approved by FDA
2919
Metacam®
(meloxicam)
1.5 mg/mL Oral Suspension
Caution: Federal law restricts this drug
to use by or on the order of a licensed
veterinarian.
Non-steroidal anti-inflammatory drug for
oral use in dogs only
Net Contents: 32 mL
NADA 141-213, Approved by FDA
Warnings: Not for use in humans. Keep this and all medications out of reach of children. Consult a physician in case of accidental ingestion by humans. For oral use in dogs only. As with any NSAID all dogs should undergo a thorough history and physical examination before the initiation of NSAID therapy. Appropriate laboratory testing to establish hematological and serum biochemical baseline data is recommended prior to and periodically during administration. For technical assistance or to report suspected adverse reactions, call 1-866-METACAM (1-866-638-2226).
US Patent 6,184,220
Metacam® is a registered trademark of Boehringer Ingelheim Vetmedica GmbH, licensed to Boehringer Ingelheim Vetmedica, Inc.
Manufactured by:
Boehringer Ingelheim
Vetmedica, Inc.
St. Joseph, MO 64506 U.S.A.
Distributed by:
Merial Limited
Duluth, GA 30096-4640 U.S.A.
Boehringer Ingelheim
MERIAL
1 2 3 4 5 6 7
8 9 10 11 12
Metacam®
(meloxicam)
1.5 mg/mL Oral Suspension
Caution: Federal law restricts this drug
to use by or on the order of a licensed
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Non-steroidal anti-inflammatory drug for
oral use in dogs only
Net Contents: 32 mL
NADA 141-213, Approved by FDA
Boehringer Ingelheim
0 12313 60152 2
Lot No.: Exp. Date:
No Coating
Indications: Metacam® Oral Suspension is indicated for the control of pain and inflammation associated with osteoarthritis in dogs.
Dosage and Administration: Metacam® Oral Suspension should be administered initially at 0.09 mg/lb (0.2 mg/kg) body weight only on the first day of treatment. For all treatments after day 1, Metacam® Oral Suspension should be administered once daily at a dosage of 0.045 mg/lb (0.1 mg/kg).
Refer to the package insert for complete dosage and administration information.
Store at controlled room temperature, 59-86°F (15-30°C).
6015166D-02-0407
Code 601521
98838
000062
Boehringer

000070

Metacam®

(meloxicam)

1.5 mg/mL Oral Suspension

Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Non-steroidal anti-inflammatory drug for oral use in dogs only

Net Contents: 100 mL

NADA 141-213, Approved by FDA

Indications: Metacam® Oral Suspension is indicated for the control of pain and inflammation associated with osteoarthritis in dogs.

Dosage and Administration: Metacam® Oral Suspension should be administered initially at 0.09 mg/lb (0.2 mg/kg) body weight only on the first day of treatment. For all treatments after day 1, Metacam® Oral Suspension should be administered once daily at a dosage of 0.045 mg/lb (0.1 mg/kg).

Contraindications: Dogs with known hypersensitivity to meloxicam should not receive Metacam® Oral Suspension. **Do not use in cats.**

Warnings: Not for use in humans. Keep out of reach of children. Refer to the package insert for complete warnings and precautions.

For technical assistance or to report suspected adverse reactions, call 1-866-METACAM (1-866-638-2226).

Refer to package insert or client information sheet for additional information.

Store at controlled room temperature, 59–86°F (15–30°C).

6015168L-01-0407 Code 601531

Take Time Observe Label Directions

Lot No: Exp. Date:

Manufactured by:
Boehringer Ingelheim Vetmedica, Inc.
St. Joseph
MO 64506 U.S.A.

Distributed by:
Merial Limited
Duluth
GA 30096-4640
U.S.A.

MERIAL

Boehringer Ingelheim

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PMS 187 PMS 2563 PMS 326 PMS 3292 Black Coating

Boehringer
Printed Side
L092697EC

No Coating
6015169D-01-0407

Metacam®
(meloxicam)
1.5 mg/mL Oral Suspension
Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.
Non-steroidal anti-inflammatory drug for oral use in dogs only
Net Contents: 100 mL
NADA 141-213, Approved by FDA

F2917

8307

Metacam®
(meloxicam)
1.5 mg/mL Oral Suspension
Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.
Non-steroidal anti-inflammatory drug for oral use in dogs only
Net Contents: 100 mL
NADA 141-213, Approved by FDA

Boehringer Ingelheim

Warnings: Not for use in humans. Keep this and all medications out of reach of children. Consult a physician in case of accidental ingestion by humans. **For oral use in dogs only.** As with any NSAID all dogs should undergo a thorough history and physical examination before the initiation of NSAID therapy. Appropriate laboratory testing to establish hematological and serum biochemical baseline data is recommended prior to and periodically during administration. For technical assistance or to report suspected adverse reactions, call 1-866-METACAM (1-866-638-2226).

US Patent 6,184,220

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MERIAL

1 2 3 4 5 6 7
8 9 10 11 12

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6015169D-01-0407
Code 601531

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Lot No :

Exp. Date:

No Coating

6015169D-01-0407
No Coating